

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s) : HOFFMANN et al.  
Serial No. : 10/533,926 (U.S. Patent Application Publication 2006-0013864)  
For : TRANSMUCOSAL PHARMACEUTICAL  
ADMINISTRATION FORM  
Filed : 17 October 2003 (PCT filing date)  
Examiner : ORWIG, Kevin S.  
Art Unit : 1611

745 Fifth Avenue  
New York, NY 10151

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

SIR:

Pursuant to 37 CFR §§ 1.56, 1.97 and 1.98, Applicants respectfully request that the Examiner consider the references listed on the attached Form PTO-1449. The Commissioner is hereby authorized to charge any additional fee which may be required, or credit any overpayment to Account No. 50-0320.

**I. Timeliness, Fees and Certifications in lieu of Fees**

- ☒ A. This information disclosure statement is being filed within three months of the filing date of the application, or within three months of entry into the national stage, or before the mailing of a first Office Action on the merits. Pursuant to 37 CFR § 1.97(b), consideration of this information disclosure statement does not require a fee or a statement under 37 CFR § 1.97(e). However, should the Commissioner determine that a fee is, in fact, due, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-0320.
- ☐ B. This information disclosure statement is being filed after the period in A above, but before the mailing of either a final action or a notice of allowance. Pursuant to 37 CFR § 1.97(c), consideration of this information disclosure statement requires a fee or a statement under 37 CFR § 1.97(e):
- ☐ 1. The Commissioner is hereby authorized to charge the fee set forth in 37 CFR § 1.17(p) to Deposit Account No. 50-0320.
- ☐ C. This information disclosure statement is being filed after the period specified in B above, but on or before the payment of the issue fee. Pursuant to 37 CFR § 1.97(d), consideration of this information disclosure statement requires a petition, which Applicants hereby request, and payment of the petition fee, which is set forth in 37 CFR § 1.17(i), and which the Commissioner is hereby authorized to charge to Deposit Account No. 50-0320. Consideration of this information disclosure statement also requires a statement under 37 CFR § 1.97(e):
- ☐ 1. Applicants hereby state that each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
- ☐ 2. Applicants hereby state that no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 CFR § 1.56 more than three months prior to the filing of this information disclosure statement.

## II. Copies of Listed References

- ☐ A. No copies of references are being provided as all references cited on Form PTO-1449 are either U.S. Patents or U.S. Patent Application Publications.
- ☒ B. Copies of all references which are foreign patents or non-patent literature listed on the attached Form PTO-1449 are being supplied.
- ☐ C. Copies of all references listed on the attached Form PTO-1449 have already been supplied during the prosecution of prior application Serial No., from which the present application claims priority pursuant to 35 USC § 120. Therefore, pursuant to 37 CFR § 1.98(d), copies of the references listed on the attached Form PTO-1449 are not now being supplied.
- ☐ D. This application is a PCT national stage application, all references listed on the attached Form PTO-1449 were cited in the international search report, and PCT/DO/EO/903 indicates that both the international search report and the copies of the references listed on the attached Form PTO-1449 are in this national stage file. Therefore, copies of the references listed on the attached Form PTO-1449 are not now being supplied.

## III. Concise Statement of Relevance

- ☐ A. All references listed on the attached Form PTO-1449 are in the English language or a parallel U.S. patent or an English abstract has been provided, and, therefore, a concise statement of relevance is not required.
- ☒ B. A concise statement of the relevance of all references listed on the attached Form PTO-1449 that are *not in the English language*, is being provided on a separate sheet.
- ☐ C. All references listed on the attached Form PTO-1449 were cited in the search report issued by the \_\_\_\_\_ Patent Office, and an English-language version of that search report, which indicates the degree of relevance found by that Patent Office, is attached.
- ☐ D. This application is a PCT national stage application, all references listed on the attached Form PTO-1449 were cited in the international search report, and a copy of that search report, which indicates the degree of relevance found by the International Search Authority, is attached.

- ☐ E. All listed on the attached Form PTO 1449 were cited during the prosecution of the prior application indicated above under II.C.

**IV. Additional Information**

- ☐ A. In addition to the references listed on the attached Form PTO-1449, Applicants wish to bring to the attention of the Examiner the following abandoned or co-pending U.S. patent applications:

[Pursuant to 37 CFR § 1.98(a)(2)(iii), copies of these applications are not being submitted.]

- ☒ B. In addition to the references listed on the attached Form PTO-1449, Applicants wish to bring to the attention of the Examiner the information provided on the attached sheet.

Consideration of the foregoing in relation to this application is respectfully requested.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: Howard C. Lee  
Marilyn M. Brogan      Howard C. Lee  
Reg. No. 31,223      Reg. No. 48,104  
745 Fifth Ave.  
New York, NY 10151  
(212) 588-0800

Statement of Relevancy for "Phosphatidylcholin" (<http://www.roempp.com/prod/index1.html>)

The entry for "Phosphatidylcholin" (German for phosphatidylcholine) includes the section "Verwendung von Lecithin" (Composition of Lecithin) which states in part "...So-called Soya-Lecithin consists of Phosphatidylcholine (40-50%), Phosphatidylethanolamine (about 10%), Phosphatidylinositol (about 5%), Phosphatidylserin (about 1-2%) as well as Sterols and Fats and Oils."